DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

APR 20 1998

TRANSMITTED BY FACSIMILE

Barbara A. Thompson, Esq.
Assistant Director, Regulatory Affairs
Glaxo Wellcome, Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Re: **NDA 20-711**
Zyban (bupropion hydrochloride) Sustained-Release Tablets
MACMIS ID #6542

Dear Ms. Thompson:

This letter is in reference to Glaxo Wellcome Inc.'s (Glaxo) submission dated April 8, 1998, of promotional materials under cover of Form FDA 2253 for Zyban (bupropion hydrochloride) Sustained-Release Tablets. This submission included one sixty-second television advertisement. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards this advertisement to be lacking in fair balance or otherwise misleading under the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specific objections are described below.

Lacking in Fair Balance

The television advertisement is lacking in fair balance or otherwise misleading because the communication of important information related to the risks associated with the use of this drug product is inadequate. During the audio presentation of the major risk information associated with the use of Zyban, there are visual presentations of falling matches, a falling lighter, and falling cigarettes. The appearance of these visual presentations interferes with the viewers' ability to listen to and process the information in the audio presentation that discloses the most important risks associated with the use of Zyban. Thus, the risk information is not presented with a prominence reasonably comparable to the presentation of the effectiveness of the drug.

Requested Action

Glaxo should immediately discontinue the use of all promotional activities that convey or contain the allegedly violative presentation identified in this letter until these allegations are resolved.

Glaxo should submit a written response to DDMAC on or before May 4, 1998, describing the steps that it has taken to ensure that the use of these materials have been suspended.

Glaxo's response should directed to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857. DDMAC reminds Glaxo that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #6542 in addition to the NDA number.

Sincerely,

Stephen W. Sherman, JD, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications